



UNITED STATES DEPARTMENT OF COMMERCE
National Telecommunications and
Information Administration
Washington, D. C. 20230

MAY 22 2003

Mr. Edmond J. Thomas
Office of Engineering Technology
Federal Communications Commission
445 12th Street, S.W.
Washington, DC 20554

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Re: Biotronik, Inc. Request for Waiver (RFW)

Federal Communications Commission
Office of the Secretary

Dear Mr. Thomas:

The National Telecommunications and Information Administration (NTIA) appreciates the opportunity to review and comment on the Biotronik Request for Waiver (RFW) seeking a permanent or interim waiver of the frequency monitoring requirements of the Medical Implant Communications Service (MICS) rules.¹

The service rules for Medical Implant Communications (MIC) devices operating in the 402-405 MHz band, including the frequency monitoring requirements, were developed with two objectives in mind: to protect the primary users (meteorological aids, such as federal radiosondes) from MICS and vice versa. The potential interference from the federal radiosondes to MIC devices not designed in accordance with the MICS frequency monitoring requirements were of particular concern to NTIA.² However, recognizing that Biotronik provided, in the RFW, additional information about device operations, we agreed to reassess our concern.

As stated in the RFW, the Biotronik devices provide three types of transmissions. The first type, transmissions resulting from certain cardiac events or changes detected by the implanted Biotronik devices, and the second type, transmissions activated manually by the implant patient, comply with the MICS rules.³ Therefore, NTIA evaluated only the potential interference that might result from the Biotronik periodic transmissions if the frequency monitoring requirements are waived.

NTIA has concluded that the periodic transmissions of the implanted Biotronik devices in the MICS would not be a threat of harmful interference to the federal radiosondes. Interference

¹ Request for Waiver, In the Matter of Biotronik Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules (March 27, 2003).

² See letter, From: Fredrick R. Wentland, Acting Associate Administrator, Office of Spectrum Management, National Telecommunications and Information Administration to Edmond J. Thomas, Chief of Office of Engineering and Technology, Federal Communications Commission (November 5, 2002).

³ See letter, From Bruce A. Franca, Deputy Chief, Office of Engineering and Technology, Federal Communications Commission, to David E. Hilliard of Wiley, Stein & Fielding and to Mark Johnson of Biotronik Inc (March 8, 2002).

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would require an improbable proximity between Biotronik implanted devices and radiosondes before the very low power (6.3 nanowatts) periodic signals can exceed the interference threshold of radiosonde receivers. Therefore, with respect to protecting radiosonde operations from the Biotronik device transmissions, as long as the low power is maintained, the frequency monitoring capability is not necessary.

At the same time, we continue to believe that given the right circumstances, the potential interference from the radiosondes to Biotronik devices is very real. Radiosondes launches and landings can occur in many parts of the United States on a regular basis. These are operated by the National Weather Service, Department of Defense and others. The radiosondes may transmit for a long period of time, possibly exceeding a few hours. Considering the deployment and operational characteristics of radiosondes (i.e. transmit power, antenna gain, antenna polarization, height of radiosondes), it is very probable that Biotronik devices operating within fairly large geographic area around these launch sites will receive interference. This interference may be temporal as the radiosonde travels with wind currents. However, if the wind patterns remain fairly constant, the interference could occur regularly with daily radiosonde release schedules. Therefore, NTIA's concern remained regarding the potential difficulties that might arise if the radiosondes interfered with the reception of critical medical data.

With regard to this aspect, Biotronik has asserted in the RFW that the MICS link "cannot be used for the purpose of immediate response to life threatening situations". An interference occurrence to the Biotronic periodic transmissions, caused by a federal radiosonde or other sources, would not affect the health or safety of an implant patient. Also, the Biotronic periodic transmissions have provisions for error checking and the transmissions are repeated six times over a period of one hour. These features of the Biotronic periodic transmissions can effectively mitigate the impact of the interference from the radiosondes. Furthermore, since a patient using a Biotronic device may travel out of range of cell operations used to relay the Biotronics data, an unsuccessful transmission is not considered an uncommon occurrence.

Therefore, NTIA is assured that a failure in the MICS link resulting from radiosonde interference could not cause any harm to an implant patient. In light of this new understanding of the Biotronik devices and their proposed operations in the MICS, NTIA can now support this RFW to operate the current line of Biotronik's cardiac implant devices and future like-devices in the MICS under the following circumstances:

- the Waiver applies to implanted devices only, and not to any external equipment;
- the Waiver is limited to the device characteristics (i.e. peak power, periodic transmission duration, and transmissions per day) discussed in the RFW;
- the Waiver authorize only non-critical communications for which failure will not impact the health and safety of an implant patient;
- the Waiver states that interference from radiosondes is a very real possibility. Therefore, the Waiver should acknowledge Biotronic's acceptance of this interference;

- the Waiver stipulates that the potential interference to the Biotronik MIC devices may occur on a regular basis in some geographic areas of the United States where radiosondes launch at pre-scheduled times that information should be provided to medical professionals regarding this possibility.

Again, we thank you for the opportunity to evaluate the Biotronik Request for Waiver of the frequency monitoring requirements of the MICS rules. If you have any questions, please contact my staff Ed Juleau at 202-482-1694 or Gerald Hurt at 202-482-4107.

Sincerely,

A handwritten signature in black ink, appearing to read "F. Wentland", with a stylized flourish at the end.

Fredrick R. Wentland
Acting Associate Administrator
Office of Spectrum Management